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**REMARKS**

Original claims 1-33 remain pending in the present application. For the reasons set forth below, reconsideration and withdrawal of each of the outstanding rejections are requested.

**Rejection Under § 101**

Claims 1-15 have been rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter. Specifically the Examiner asserts that (1) product is not properly identified and (2) process and/or product does not have an asserted utility. This rejection is respectfully traversed.

Claim 1 recites the formation of "an intermediate-carbazolone reaction mixture." This product is defined on page 10 of the present specification and is believed to contain an amine-carbazolone and/or an exocyclic methylene compound as described on pages 7 and 8. Regardless of the precise composition, the intermediate-carbazolone reaction mixture is useful as an intermediate in forming ondansetron. Thus, as recognized by the Examiner, the product of the process of claim 1 is clearly useful in making ondansetron. Because a utility has been asserted (and demonstrated in the Example) for the process and product produced by claim 1, the Examiner's assertion that no utility has been asserted is plainly in error. Accordingly, claims 1-15 define useful, statutory subject matter.

The fact that the product of claim 1, e.g. the intermediate-carbazolone reaction mixture, is not defined by a structural formula and/or that the process as claimed may not fit nicely into the USPTO classification system does not negate the utility of the claimed subject matter. Indeed, there is no requirement under 35 U.S.C. that the claims recite a structural formula or that the claims be drafted so as to assist the Examiner's search of the

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prior art. See *Ex parte Tanksley*, 37 USPQ2d 1382 (BPAI 1994); *Ex parte C*, 27 USPQ2d 1492 (BPAI 1992).

In view of the Examiner's admitted understanding that the intermediate-carbazolone reaction mixture is useful in making, *inter alia*, ondansetron, the claimed process has utility within the meaning of 35 U.S.C. § 101. Reconsideration and withdrawal of this rejection are requested.

**Rejection Under § 112, 1<sup>st</sup> paragraph**

Claims 1-15 have been rejected under 35 U.S.C. § 112, first paragraph, as lacking a use. This rejection is respectfully traversed.

For the reasons set forth above, claims 1-15 clearly define a useful process, namely a useful process for making an intermediate composition suitable for making ondansetron. Having taught how to use the intermediate-carbazolone reaction mixture to make ondansetron, the present rejection is in error. Reconsideration and withdrawal are requested.

**Rejection Under § 112, 2<sup>nd</sup> paragraph**

Claims 1-15, 18, and 30 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. This rejection is respectfully traversed.

Regarding claims 1-15, the Examiner has failed to state how the claims are indefinite and thus has not met his burden in making a rejection. In reality, the metes and bounds of claims 1-15 are reasonably precise. Nothing further is required under § 112, second paragraph.

Regarding claim 18, the words "simultaneously" and "substantially" are used in the ordinary sense, the latter modifying the former. This means that the imidazole

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compound is provided around the same time as the formation of the reaction mixture as opposed to being provided, for example half an hour after the intermediate-carbazolone reaction mixture is formed. The compound is "provided" in the reaction mixture by any suitable means such as by addition to or combining with the reaction mixture or a precursor mixture thereof. In as much as these words are commonly used, the worker of ordinary skill in the art would readily understand the boundary of claim 18 with reasonable precision.

Regarding claim 30, the verb "converting" is not functional language, but rather a step in the claimed process. The Examiner's allegation that a skilled artisan would not be enabled to convert ondansetron to a salt is preposterous. In any event, the second paragraph of § 112 does not have an enablement requirement and the instant rejection is clearly in error.

In view of the above, all claims reasonably define the scope of the subject matter to be patented and are thus in full compliance with § 112, second paragraph.

Reconsideration and withdrawal of this rejection are requested.

#### Rejection Under § 102 Over CN 1110970A

Claims 1-6, 10-12, 15-18, 24, and 31 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by CN 1110970A to Juping et al ("CN '907"). This rejection is respectfully traversed.

The Examiner fails to allege that CN '970 teaches a "water binding agent" as required by claim 1. Indeed, the presence of a water binding agent in the present invention allows for various advantages including faster reaction times; yet this feature is missing in CN '970. Perhaps the Examiner has confused acetic acid with the water

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binding agent acetic anhydride, also known as acetic oxide. Acetic acid is not a water binding agent. In any event, CN '970 does not teach or suggest forming a reaction mixture with a water binding agent or reacting a carbazolone in such a mixture as per claim 1. Therefore, CN '970 does not identically describe the claimed subject matter and reconsideration and withdrawal of this rejection are requested.

**Rejection Under § 102 Over US 4,695,578**

Claims 1-23, 25-29, and 31-33 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by US 4,695,578 to Coates et al ("Coates"). This rejection is respectfully traversed.

Again the Examiner fails to allege that a water binding agent is taught or suggested by the applied prior art. Nothing in columns 6, 7, or 9 nor in corresponding example 11 teaches or suggests the use/presence of a water binding agent. In the absence of a teaching of this claimed feature, the disclosure in Coates fails to anticipate the claimed subject matter. Accordingly, reconsideration and withdrawal of this rejection are requested.

**Rejection Under § 102 Over CN 1105994A**

Claim 30 has been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by CN 1105994A to Jichang et al ("CN '994"). This rejection is respectfully traversed.

While CN '994 does show the conversion of ondansetron to a salt, the Examiner has failed to even allege that a water binding agent is present in the reaction mixture as per parent claim 1. Thus again the Examiner has overlooked this feature of the present invention. Having failed to find each and every element of the claimed process in CN

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'994, the rejection is in error. Reconsideration and withdrawal of this rejection are requested.

#### **Rejection Under § 103 Over US 4,695,578**

Claims 2, 4, and 6-8 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Coates.<sup>1</sup> This rejection is respectfully traversed.

As pointed out above, Coates fails to teach or suggest the use of a water binding agent. Indeed, Coates shows no aversion to the presence of water and uses it in the imadazole reaction step in Example 7.

Moreover, Coates shows that the reaction times using such conventional reactions is rather lengthy; 20 hours in Example 7 and 42 and 43 hours in Example 11 steps (i) and (ii) in forming an analogous compound to ondansetron. In contrast the present invention can be carried out more quickly.

Coates fails to teach or suggest a water binding agent and certainly fails to teach or suggest any advantages such as faster reaction rates that could be obtained thereby. Accordingly, the formation of the presently claimed invention could not have been obvious over the teaching in Coates. Reconsideration and withdrawal of this rejection are requested.

#### **Conclusion**

In view of the above arguments, the presently claimed subject matter is novel and unobvious over the applied prior art. Reconsideration and withdrawal of the rejections and allowance of the present application are respectfully requested.

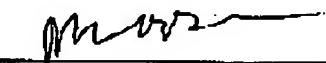
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<sup>1</sup> While the formal statement of the rejection refers to a Mueller US 4,480,124, the text of the rejection refers to the previously cited Coates patent. Since Mueller deals with purifying glycols, applicants have assumed that Coates was the intended patent.

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Should the Examiner have any questions regarding this application, he is encouraged to contact Mark R. Buscher (Reg. No. 35,006) at telephone No. 703 753 5256.

Respectfully submitted,

  
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